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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/991,283	11/13/2001	Elliott Farber	14358-316	3855
24633	7590	06/03/2004	EXAMINER	
HOGAN & HARTSON LLP IP GROUP, COLUMBIA SQUARE 555 THIRTEENTH STREET, N.W. WASHINGTON, DC 20004			SHARAREH, SHAHNAM J	
			ART UNIT	PAPER NUMBER
			1617	

DATE MAILED: 06/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/991,283	Applicant(s) FARBER, ELLIOTT	
	Examiner Shahnam Sharareh	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 November 2001, 2/10/04
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-173 is/are pending in the application.
- 4a) Of the above claim(s) 22-136 and 151-158 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21, 137-150 and 159-173 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/17/03, 4/7/03, 3/21/02, 2/25/02</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-173 are pending.

Election/Restrictions

1. Applicant's election of species of an emulsifying system of anionic emulsifiers with acidic waxes on Feb 10, 2004 is acknowledged. Applicant's election of epidermolysis bullosa as the skin condition, on Feb 10, 2004 is also acknowledged. Claims 1-21, 137-150, 159-173 are directed to the elected species, and the search is conducted towards the elected species.
2. Claims 22-136, 151-158 are withdrawn from further consideration as being drawn to a nonelected species. Applicant is informed that if the Markush-type claim is not allowable over the prior art, examination will be limited to the Markush-type claim and claims to the elected species, with claims drawn to species patentably distinct from the elected species held withdrawn from further consideration (see MPEP 803.02).

To the extent that claims read on the elected species and methods of treating skin conditions wherein the skin condition is epidermolysis bullosa, claims are found to be free of art. However, the search was then extended to include skin conditions such as decubitus ulcer or diabetic ulcers.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-4, 7-8, 11 rejected under 35 U.S.C. 102(b) as being anticipated by Kuroda JP 58-140013 (translated copy).

Kuroda et al teaches compositions and methods of applying a composition comprising allantoin, an anionic emulsifier, and a wax. Kuroda also teaches compositions having prolonged stability of about 90 days when pH levels of the composition is adjusted below 5.5 (translated copy, page 2, 2nd and 3rd paragraph; table 2, page 6). Kuroda states that emulsion preparations such as ointments and creams may contain suitable anionic surfactants such as sodium alkylsulfates (translated copy, page 3, 1st paragraph). Kuroda states that allantoin is an old compound which is commonly used for treatment of various skin ailments such as cuts, burns, as well as, inflammatory skin conditions such as eczema (see translated copy page 2, 1st paragraph). The waxes of Kuroda include paraffin and Vaseline.

Applicant's is informed that in a claim drawn to a process, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Accordingly, since Kuroda teaches method of applying his compositions to skin, he also inherently anticipates the intended use of the instant claims, namely for treating skin conditions such as epidermolysis bollusa. Accordingly, Kuroda anticipates the limitations of the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
4. Claims 1-4, 7-8, 11, 137-140, 143-148, 150, 159-167, 169 are rejected under 35 U.S.C. 103(a) as being unpatentable over of Kuroda et al JP 58-140013 (translated copy) in view of Magraf et al (archives of Surgery, 1977; 112 (6): 699-704), Bar-On et al US Patent 5,122,533.

The teachings of Kurado are described above. Kurado fails to teach the instantly recited acidic wax as in claim 5 and Kuroda compositions lack various emollients and herbal extracts of the instant claims.

Magraf and Bar-on teaches the therapeutic benefits of allantoin in treating necrotic tissues (abstract). Magraf teaches that allantoin stimulates the growth of healthy tissue and derbies necrotic tissue (see page 699, 1st col, 2nd paragraph). Margraf teaches the efficacy of allantoin containing cream in treating diabetic ulcers in

92 patients (see page 701, table 3; page 702, fig 3). Margraf acknowledges the use of corticosteroids in treatment of vascular skin ulcer (page 703, 2nd paragraph). Margraf further states that the vehicle of any topical agent plays a paramount role on the end clinical outcome (see page 704, 3rd paragraph). Accordingly, the use of allantoin for treatment of inflammatory skin conditions such as diabetic foot ulcer is well recognized in the art. Margraf fails to teach a suitable delivery system containing allantoin.

Bar-on teaches suitable allantoin delivery systems comprising allantoin and an anionic surfactant (col 4, lines 20-50) for treatment of necrotic tissues. Bar-On doesn't use bees wax in his composition.

5. Although Kurado fails to specifically teach the use of his allantoin with acidic waxes such as beeswax for treatment of various ulcerogenic skin conditions, it would have been obvious to one of ordinary skill in the art at the time of invention to use Kurado composition to improve the recovery of any skin suffering from ulcerogenic skin conditions such as diabetic foot ulcer, because as taught by Magraff and Bar-On, the ordinary skill in the art would have had a reasonable expectation to succeed in stimulating the growth of healthy tissues in such ulcers using the effective delivery formulations of Snyder.

Finally, using an adjunct corticosteroid regimen with allantoin formulation in treating ulcerated tissue would have also been obvious, because as taught by Margraf, the ordinary artisan would have had a reasonable expectation of observing cumulative therapeutic effect.

6. Claims 1-21, 137-150, 159-173 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuroda et al JP 58-140013 ('JP 013) (see entire translation) in view of Magraf et al (archives of Surgery, 1977; 112 (6): 699-704), Bar-On et al US Patent 5,122,533 and further in view of Grollier et al US Patent 4,767,618.

The teachings of JP '013 are described above. JP provides for the use of his compositions for ulcerogenic skin diseases. Magraf and Bar-on elaborates on the use of allantoin and corticosteroids for use as anti-inflammatory agent as described above. The combination of JP '013, Magraf and Bar-on does not teach the specific ingredients such as beeswax, various instantly recited herbal components such as St. Johns' wort, arnica extract or chamomile extract and carbohydrate polymers.

Grollier is used to provide the deficiency of the combined teachings of JP '013, Magraf and Bar-on. Grollier discloses oil-in-water emulsion compositions that can contain beeswax as a component, which assists oil retention (see col 6, lines 53-56; col 5, line 49). Grollier also teaches the use of herbal components in such oil-in-water emulsions. The herbal components taught by Grollier include St. John's wort, chamomile, arnica, or witch hazel (col 3, lines 30-31, 46-56) that can be in the form of powder or extract (see col 2, lines 4-15; col 6, lines 61-64). Grollier also provides for the use of various carbohydrate thickeners such as guar gum, cellulose derivatives, etc. (col 5, lines 48-65). Grollier also suggests the use of suitable anionic surfactants such as sodium lauryl sulfate as emulsifying agents (see col 6, lines 5-13), lanolin oil, and cod liver oil as the oil phase (see col 5, line 27-30; col 6, line 40-41), propylene glycol or cetyl alcohol as solvents (col 5, lines 5-12; col 16, lines 30-35), perfume of choice, anti-

inflammatory and antiseptic such as allantoin (col 16, line 34-35), a pH modifier, antioxidants such as butyl hydroxyanisole, and preservative agents such as methyl parahydroxybenzoate (methylparaban, see RN 99-76-3), or propyl parahydroxy benzoate (propylparaben, see RN 94-13-3) (see col 6, lines 56-60; col 14, lines 20-23). Grollier compositions are essentially in the form of emulsions (col 7, lines 9-21).

7. Accordingly, since it has been held that the selection of known material based on its suitability for its intended use supported a *prima facie* obviousness determination in *Sinclair & Carroll co. V. Interchemcial Corp.*, 325 U.S. 327, 65 USPQ 297 (1945), it would have been obvious to one of ordinary skill in the art at the time of invention to further modify the JP '013 emulsions by adding cosmetic components of interest including oil retention agents such as beeswax, and suitable herbal components of choice such as chamomile or St. John's wort, and any art equivalent carbohydrate thickeners as taught by Grollier, because the ordinary skill in the art would have had a reasonable expectation of success in improving the properties of the JP '013 emulsions for its intended utility and further apply such formulations to treat the skin disease of interest.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1-21, 137-150, 159-173 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13-26 of copending Application No. 10/322,797. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to similar subject matter namely methods of treating skin conditions using allantoin compositions comprising allantoin and an emulsifying system, accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to practice the scope of each set of claims when in possession of one of them.

9. Claims 1-21, 137-150, 159-173 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1-10 of U.S. Patent No. 6,673,826 and claims 1-25 of 6,531,500. Although the conflicting claims are not identical, they are not patentably distinct from each other because they overlap in scope, as both sets of claims are directed to methods of treating epidermolysis bullosa and one of ordinary skill in the art in possession of the patented claims would have also practiced the instantly claimed inventions.

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose

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telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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